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EXAMINER	
TRAN, SUSAN T	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 16

Application Number: 09/940,784
Filing Date: August 28, 2001
Appellant(s): HASLWANTER ET AL.

Robert A. Franks
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 08/04/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 15-33 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,728,509	Shimizu et al.	03-1988
5,015,474	Parnell	05-1991
5,116,847	Gilbert et al.	05-1992

Rybacki et al., "Auxiliary Substances in Technology of Drug Form", Library of a Pharmacist, Vol. 7, pages 1-12, 1980.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-17, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 4,728,509, in view of Gilbert et al. US 5,116,847 and Parnell US 5,015,474.

Shimizu teaches nasal aqueous liquid preparation having pH between 5 and 8, the formulation comprising drug and 0.2-20 % (w/v) of polyvinylpyrrolidone (PVP) having average MW of about 25,000-120,000, cyclodextrin, phosphate buffer, propylene glycol, benzyl alcohol, sodium phosphate, and thickener (columns 1-2, and examples 2-3).

Shimizu is silent as to the teaching of the specific drug, and other carriers as claimed in claims 2-8.

Gilbert teaches nasal spray composition comprising active agent, such as chlorpheniramine maleate, oxymetazoline hydrochloride; benzalkonium chloride; polyethylene glycol; and solubilizing agent such as cyclodextrin (columns 6-8).

Shimizu does not teach the use of two or more PVP.

Parnell teaches nasal spray composition comprising drug, preservative, benzyl alcohol, polyethylene glycol, PVP as thickener, EDTA, and buffer (columns 4-5). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Shimizu's formulation with the active drug, and the aqueous carriers in view of the teachings of Gilbert, and PVP as thickening agent in view of the teaching of Parnell to obtain the claimed invention, because the references teach the advantageous results in the use of aqueous nasal formulation useful for the treatment of respiratory diseases, such as allergy, itchy nose, and runny nose. The expected result would be an aqueous nasal spray formulation comprising oxymetazoline HCl and PVP that is stable, alleviate dryness, and reduce nose-irritation.

Claims 18-20, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al., in view of Gilbert et al., Parnell, and Rybacki et al. (Library of a Pharmacist, vol. 7).

Shimizu, Gilbert, and Parnell are relied upon for the reason stated above. The references are silent as to the specific molecular weight of PVP being claimed.

Rybacki teaches PVP having molecular weight of about 10,000, 40,000, 160,000, and 360,000 are useful in pharmaceutical art as a binder, solubilizer, and thickener (pages 8-10). Thus, it would have been obvious for one of ordinary skill in this art to modify Gilbert's formulation using PVP having the molecular weight of Rybacki with the expectation of at least similar result, because the references teach that PVP is useful in liquid nasal formulation.

Response to Arguments

Appellant argues that absent the mention in a reference of record that a combination of two or more polyvinylpyrrolidone polymers having different average molecular weights would be useful in a nasal spray composition, there simply can be no *prima facie* case for obviousness of claims 15-17 and 21-28. In response to appellant's argument, although Shimizu does not teach mixture of PVP having different average molecular weights, the examples of Shimizu suggest using polyvinylpyrrolidone having different average molecular weights for similar purpose desired by the appellant, *e.g.*, stable aqueous solution with *great effectiveness* (column 1, lines 55-57). Therefore, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation combine the PVP polymers in the examples to obtain the claimed invention. Accordingly, no criticality is seen in the use of the particular mixture of PVP polymers having different average molecular weights since the Shimizu obtains similar result desire by the appellant, *e.g.*, a stable nasal drop

preparation with great effectiveness, excellent anti-allergic action and anti-inflammatory action (column 3, lines 1-5).

Appellant argues that no conceivable combination of teachings from these patents would render the appellant's claims obvious. It is not possible to find all of the claim limitations in a combination of teachings over Shimizu et al., in view of Gilbert et al., and Parnell. In response to applicant's argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Furthermore, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Gilbert is relied upon for the teaching that nasal spray composition can be used to administered the claimed drugs (active agents). Parnell is relied upon solely for the teachings that more than one polymer can be used as additive agents in a nasal spray composition.

Appellant argues that the Final Office Action reflects an improper use of the Rybacki et al. document, because the majority of the discussion concerning PVP is directed toward uses of the polymers to obtain desirable properties in solid pharmaceutical dosage forms; some of this discussion specifies the use of solutions of the polymer. Contrary to the appellant's argument, the term "pharmaceutical formulation" suggests in Rybacki is a generic term, and therefore, it includes nasal composition.

Appellant argues that nothing in the Rybacki et al. publication assists in overcoming the fundamental deficiency of the combined patent documents: the combination still does not include teachings of mixture of two or more polyvinylpyrrolidone having different average molecular weight. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Rybacki is cited in combination with Shimizu, Gilbert, and Parnell. Rybacki is relied upon solely for the teaching of the molecular weight of PVP that is useful in pharmaceutical composition.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

S. Tran
September 29, 2003

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